

SAFETY DATA SHEET COMPLEX FERTILIZERS, NPK TYPE

According to EC Regulation no. 1907/2006 (REACH) / EC Regulation no. 1272/2008/ Regulation no. 830/ 2015.

SECTION 1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND THE COMPANY

1.1. Product identification

Name: COMPLEX FERTILIZERS NPK, NP OR NK TYPE
Other names: COMPLEX FERTILIZERS
Chemical formula: -
CAS number: -
EINECS number: -
ECHA reference number: for ammonium nitrate: 01- 2119490981- 27- 0064
ammonium sulphate: 01- 2119455044- 46- 0098
ammonium dihydrogenorthophosphate: 01- 2119488166- 29- 0047
diammonium hydrogenorthophosphate: 01- 2119490974- 22- 0044
potassium sulphate: 01- 2119489441- 34- 0029
calcium carbonate: 01- 2119486795- 18- 0070
calcium hydrogenorthophosphate: 01- 2119490064 - 41 - 0017

1.2. Relevant identified uses of the substance or mixture and uses advised against

Identified uses: chemical fertilizer

Uses advised against: none

1.3. Details concerning the supplier of the Safety Data Sheet

Producer:

Azomureș S.A.Tg.-Mureș, 300 Gheorghe Doja St., tel.0040-265 253 700, Romania

Fax: 0040-265 252 986, e-mail: office@azomures.com, www.azomures.com

e-mail (competent person responsible for the SDS): fds.azo@azomures.com

1.4. Emergency telephone number

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The institution responsible with providing information in case of a health emergency is The National Institute for Public Health, Department for the International Sanitary Regulation and Toxicological Information.

Telephone: 0040-21.318.36.06, working hours: Monday – Friday from 8 a.m. to 3 p.m.

SECTION 2.	HAZARDS IDENTIFICATION
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2.1. Classification of the substance or mixture
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Complex fertilizers NPK, NP or NK type are inorganic, multi-constituent substances.

Complex fertilizers NPK, NP or NK type which have a higher ammonium nitrate content of 70% (ex.: 26-13-0; 27-13,5-0; 26-5-5; 27-6-6) are considered hazardous during transportation, according to ADR, RID and IMDG provisions.

The hazard of these sorts is given by the concentration of ammonium nitrate (higher concentration than 70%), also determining the CLP classification.

Classification according to EC Regulation no. 1272/2008 (CLP)

The classification according to CLP Regulation no. 1272/2008 is that for ammonium nitrate, as the concentration level exceeding 70% makes the 27-6-6; 26-5-5; 26-13-0; 27-13,5-0 sorts hazardous.

Hazard Classes/Categories: Oxidizing solid, Class 3

Serious damage of the eyes/irritation of the eyes, Class 2

Hazard statements H: H 272 - May intensify fire; oxidizer

H 319 - Causes serious eye irritation

Human health hazard

This product is not dangerous if handled accordingly.

Nevertheless, the following aspects will be taken into consideration:

Skin contact: may cause irritation in case of prolonged contact

Eye contact: may cause irritation in case of prolonged or repeated contact

Ingestion: no toxic effects in case of small quantities, in large quantities it may cause gastrointestinal disorders, and, in extreme cases (especially in children) it may cause methaemoglobinaemia, the "blue baby syndrome" and cyanosis (blueness around the mouth).

Inhalation: large quantities of dust containing this product may cause irritation of the nose and airways; the symptoms include sore throat and cough.

Environmental hazards

No environmental hazard assessment was conducted as ammonium nitrate presents little danger for aquatic organisms.

Due to the reduced hazardous potential on aquatic organisms, and its main effect, eutrophication, the substance is not considered dangerous for the environment, according to Community/national Regulations.

Ignition or explosion hazard

The fertilizer itself is not combustible, but it may sustain combustion even in the absence of air.

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At approx. 170 °C the substance melts, slowly decomposing into ammonia and nitric acid.

At over 200 °C the decomposition is accelerated and the decomposition reaction may turn into a chain reaction if no immediate measures for cooling are taken, by spraying a maximum quantity of water (actual flooding). Decomposition products (nitrogen oxides) catalyze the reaction, causing an explosion.

At high temperatures (over 400 °C) the fertilizer may ignite and burn, with simultaneous decomposition in nitrogen oxides. The decomposition may cause an explosion in case of contamination with incompatible materials, such as: fuels (gasoline, Diesel fuel), lubricants (petrolatum, oils), metallic powders and other materials specified in section 10.5.

2.2. Labelling

Labeling according to CLP Regulation

Substance name: COMPLEX FERTILIZER CONTAINING AMMONIUM NITRATE

Producer:

Azomureș S.A.Tg.-Mureș, 300 Gheorghe Doja St., tel. 0040-265 253 700, Romania

Fax: 0040-265 252 986, e-mail: office@azomures.com, www.azomures.com

Emergency telephone number: 0040-21.318.36.06, working hours: Monday - Friday from 8 a.m. to 3 p.m.

Hazard labels: symbols

GHS03 - flame over a circle

GHS07 - exclamation point

Warning word: Attention!



GHS03 - Oxidizer solid, class 3



GHS07 - Eye irritation, class 2

Hazard statements H: H 272 - May intensify fire; oxidizer

H 319 - Causes serious eye irritation

Precautionary statements: Prevention

P210 - Keep away from heat/sparks/open flames/hot surfaces. No smoking.

P220 - Keep/Store away from clothing/combustible materials (lubricants, Diesel fuel, oil, paints etc.)

P264 - Wash hands thoroughly after handling

P280 - Wear protective gloves (heat resistant)/protective clothing (powder resistant overalls)/tight safety goggles/ face mask

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Intervention

P 370 + P 378 - In case of fire use plenty of water (flooding). Use dust or carbon dioxide extinguishers for cooling;

P 305+351+338 - If in eyes: Rinse cautiously with water for several minutes
Remove contact lenses, if present and easy to do. Continue rinsing.

P 337+ P313 – If irritation persists see the doctor

EU label (according to ADR)

Substance name: COMPLEX FERTILIZER CONTAINING AMMONIUM NITRATE

Producer:

Azomureș S.A.Tg.-Mureș, 300 Gheorghe Doja St., tel.004-0265 253 700, Romania

Fax: 004-0265 252 986, e-mail: office@azomures.com, www.azomures.com

Emergency telephone number: 021.318.36.06, working hours: Monday - Friday from 8 a.m. to 3 p.m.

Class 5.1 - oxidizing substances

Content: ammonium nitrate >70%AA - < = 98.5% AA

Net weight of the fertilizer

Hazard symbol:



2.3. Other hazards

According to Annex XIII of the EC Regulation no. 1907/2006, the PBT and vPvB assessment has not been conducted because ammonium nitrate is an inorganic substance.

Other hazards: not known.

SECTION 3. COMPOSITION / INFORMATION ON INGREDIENTS

3.1. Chemical identity of the substance

The product must be considered: Substance

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COMPLEX FERTILIZERS CONTAINING AMMONIUM NITRATE - a multi-constituent substance

Composition: ammonium nitrate - CAS: 6484-52-2
ammonium sulphate - CAS: 7783-20-2
calcium hydrogenorthophosphate - CAS: 7757-93-9
ammonium dihydrogenorthophosphate - CAS: 7722-76-1
diammonium hydrogenorthophosphate - CAS: 7783-28-0
potassium sulphate - CAS: 7778-80-5
calcium carbonate - CAS: 471-34-1
potassium chloride - CAS: 7447-40-7

Ammonium nitrate (hazardous in concentrations > 70%)

CAS number: 6484-52-2

EINECS number: 299-347-8

IUPAC name: ammonium nitrate

Molecular formula: H₃N.HNO₃

SMILES notation: [NH₄⁺].[O⁻] [N⁺](=O)[O⁻]

Molecular weight range: 80.0434

ECHA reference number: 01- 2119490981- 27- 0064

Typical concentration: >= 32% - < =75% (w/w)

Chemical identification of impurities

Calcium phosphate - CAS number: 10103-46-5

EINECS number: 233-283-6

Typical concentration: depending on the sort

Concentration limit: >=0 - <=1% (w/w)

Water - CAS number: 7732-18-5

EINECS number: 231-791-2

IUPAC name: water

Typical concentration: >=0.15% - <=0.45% (w/w)

Calcium fluoride - CAS number: 7789-75-5

EINECS number: 232-188-7

Typical concentration: depending on the so

Concentration limit: >=0 - <=7% (w/w)

SECTION 4. FIRST AID MEASURES

4.1. Description of the first aid measures

4.1.1 First aid instructions are provided depending on the relevant exposure routes.

Skin contact: rinse the affected area with plenty of water. Remove contaminated clothing and shoes.

In case symptoms occur, seek medical advice.

Eye contact: rinse/irrigate eyes with plenty of water for 10 minutes; if irritation persists, seek immediately medical advice.

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Ingestion: in case of ingesting the product, rinse mouth with water (only if the victim is conscious).

Do not induce vomiting. In case symptoms occur, seek medical advice.

Inhalation: in case of inhaling the product, remove victim to fresh air. In case symptoms occur, seek medical advice.

4.1.2 Recommendations:

Remove the victim from the area contaminated with dust or gas, keep the victim at rest in a warm area, even in the absence of symptoms; administer oxygen, especially in case of blueness around the mouth; artificial respiration must be used only as a last resort, in case of prolonged exposure.

4.2. The most important symptoms and effects, acute as well as delayed

Keep under medical observation for at least 48 hours, in order to prevent the development of a pulmonary edema or methaemoglobinaemia.

4.3. Indications concerning any emergency medical assistance and necessary special treatments

Note for the attending doctor: methaemoglobinaemia

SECTION 5. FIREFIGHTING MEASURES

5.1. Fire extinguishing means

Adequate extinguishing means

Small fires

The substance is not combustible. This product may sustain combustion. Use water to extinguish the fire.

Large fires

The substance is not combustible. This product may sustain combustion. Use water to extinguish the fire.

Inadequate extinguishing means

Do not use chemicals or foam to extinguish the fire, use sand or soil for emerging fires, if there is no water source available.

5.2. Special hazards caused by the substance or mixture

Unusual fire and explosion hazards

The substance may be explosive in contact with flammable or organic substances, or if it is confined during the fire.

Hazardous decomposition products and combustion products

In case of fire, hazardous decomposition products may be generated, such as nitrogen oxides (NO, NO₂ etc.), ammonia (NH₃), amines.

Special procedures for fire extinguishing

Special measures are not necessary.

Wear adequate protection equipment. Use a self-contained breathing apparatus.

5.3. Advice for firefighters

Special procedures for fire extinguishing

Special measures are not necessary.

Wear adequate protection equipment. Use a self-contained breathing apparatus.

SECTION 6. ACCIDENTAL RELEASE MEASURES

6.1. Personal precautions, protective equipment and emergency procedures

6.1.1 For personnel not involved in emergency situations

(a) Protective equipment

Hand protection:

Protective gloves (heat resistant).

Eye protection:

Face protection equipment - tight safety goggles (plastic frame, polycarbonate lens) for chemical substances.

- face mask (polycarbonate) - in case of danger of nitrate splashes

Skin protection

Protective clothing:

Dust resistant overalls (breastplate duck overalls, coat).

Winter or summer shirt (natural fibers - duck)

Protective footwear:

Chemical and mechanical aggression resistant boots, with anti-static properties that allow usage in explosive environments (leather with rubber soles).

(b) Keep away from heat and fire sources

Use a self - contained breathing apparatus and adequate equipment for firefighting.

Open doors and windows to produce maximum ventilation of the room.

(c) Emergency procedures

In case of great danger, the surrounding area must be evacuated.

Avoid inhaling toxic fumes by standing up wind from the fire.

6.1.2. For the personnel involved in emergency situations

The personnel involved in emergency situations must wear duck, dust resistant equipment, chemical aggression resistant boots and protection mask.

6.2. Precautions for the environment

Avoid contamination of the soil and groundwater courses.

6.3. Methods and material for containing fires and for cleaning

Containment and cleaning method for the dispersed substance

Dispersion and leakage of small quantities

Vacuum or collect the product in special containers, marked as waste. Clean the contaminated area using a large quantity of water. In case the spilled substance reaches into watercourses, inform local authorities.

Dispersion and leakage of large quantities

Vacuum or collect the products in special containers, marked as waste. Recycle if possible. Clean the contaminated area with a large quantity of water. In case the spilled substance reaches into watercourses, inform local authorities.

Inadequate techniques for containment and cleaning

Do not contain the spilled product using sawdust or any other combustible material.
Do not use plugs made from organic materials, such as wood, in order to stop leakage.

6.4. Reference to other sections

Note: see chapter Exposure control / individual protection, for information concerning personal protection equipment and the section Disposal considerations.

SECTION 7. HANDLING AND STORAGE

7.1. Precautions for safe handling

7.1.1 Recommendations for safe handling

Use adequate ventilation. A local exhaust ventilation system must be provided. Avoid all possible ignition sources (spark or flame). Avoid contamination with any source, including metals, dust or organic substances.

7.1.2 Recommendations concerning good general hygiene practices at the work place

- Do not eat, drink or smoke in the working area. "NO SMOKING" signs are to be placed in the working area.
- Wash hands thoroughly after each use.
- Remove contaminated clothing and protection equipment before entering lunch areas.

7.2. Safe storage conditions, including possible incompatibilities

The product will be stored in confined spaces, dry, clean, well ventilated and away from heat and fire.

Stacking of bags should be made in such a way that any danger is avoided.

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The storage spaces should preferably be single level and be constructed of brick, concrete, not from combustible materials (like wood); the flooring must be flat, dry and smooth, without cavities.

The storage facilities must provide a good protection for the fertilizers against bad weather and avoid humidity absorption.

The storage facility must be cleaned before, during and after delivery of the product.

The ambient conditions in the storage facilities are monitored: temperature and humidity.

It is forbidden to store ammonium nitrate fertilizers together with: products which decompose through explosion such as organic peroxides; flammable liquids: combustibles, oils, greases; pressure gas cylinders; corrosive agents; chromates; chlorates; hypochlorites; nitrites; permanganates etc.; pesticides based on synthetic organic compounds; hay, straw, paper, wood residues, metal powders, alkaline substances which in contact with the ammonium nitrate may discharge ammonia; insecticides, pesticides, disinfectants etc.

Avoid contact with combustible substances and reducing agents. Do not expose the substance at high temperatures. Smoking and open fire is forbidden in storage spaces.

Fertilizers should not be stored together with other products.

The product is packed in polyethylene bags or double bags (polyethylene and polypropylene). Polyethylene bags are closed by welding, plying or sewing together with polypropylene bags and the polypropylene bags are closed by sewing.

The product is usually packed in 50 kg bags, but it may also be packed in 40 kg, 500 kg, 600 kg or 1000 kg bags, or it may be transported in bulk, in wagons covered with a waterproof, nonflammable cover, or in metallic TALS wagons.

According to the provisions of EC Regulation no. 1272/2008, package labeling will include the following legible items: substance name, producer's full name and address, nominal weight, product identifiers, symbols referring to hazard labels, warnings, hazard statements (H), precautionary statements (P).

Labels on the bag and accompanying documents must be edited in the official language of the Member State where the product marketed, unless the contract stipulates another international language. Packed chemical products are identified by the data on the label or the package. Identification data for the product delivered in bulk or in packages that exceed 100 kg are mentioned in accompanying documents.

7.3 Specific end use (s)

Specific end uses - chemical fertilizer.

SECTION 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

8.1. Control parameters

No official limits are specified.

Values recommended by ACGIH (1995-1996) for inhalable particles:

TLV/TWA: 10mg/m³

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Relevant DNEL / DMEL values and NOAEL values are provided in the CSA for ammonium nitrate depending on the type of exposure for workers in an industrial setting and for the general public. As no acute toxicity hazard was identified, that would lead to the classification of the substance according to CLP Regulation, the long-term DNEL value is considered sufficient to ensure that no effects occur from acute exposure to the substance.

No local effects were observed after dermal and inhalation exposures and no DNEL value for local effects was derived.

Repeated dose toxicity

Long-term systemic effects - dermal - DNEL: 21.3 mg/kg bw/d
NOAEL: 255.6 mg/kg bw/d
- inhalation - DNEL: 37.6 mg/m³
NOAEC: 451.2 mg/m³

DNEL values for human exposure are derived according to ECETOC guideline (final draft).

- a) Workers exposure - dermal - DNEL: 21.3 mg/kg bw/d
- inhalation - DNEL: 37.6 mg/m³
- b) Exposure of the general public - dermal - DNEL: 12.8 mg/kg bw/d
- inhalation - DNEL: 11.1 mg/m³
- oral - DNEL: 12.8 mg/kg bw/d

8.2. Exposure control

The information related to exposure control are provided in the Exposure Scenarios attached to the Safety Data Sheet.

8.2.1 Adequate technical controls

General measures at company level

The CSSM (The Committee for Work Health and Safety) was constituted at the company level, where the risk factors of professional injury and illness in the work place are assessed.

The evaluation of the risks of professional injury and illness at the work place was carried out by committees established by the management; preventive measures were taken to eliminate or to diminish the risks that cannot be avoided, having as purpose the work safety and health, reduction of work injuries and of professional illnesses.

The Chemical Plant:

- Risk evaluation when using dangerous chemical substances
- Ammonium Nitrate Plant II-III-ADEX (operation – chemists, packing machinists)

As a result of the analysis and evaluation of the risks at the work place:

The plan for prevention and protection at company level was elaborated and approved

A record is held of the work places of great danger and imminent danger of injury

A situation of the hazardous chemical substances used in the work process is kept

The toxic gases, released by chemical substances at the work place, are monitored.

The health of the staff exposed to the action of chemical substances is supervised and monitored

The auditing of the safety and health at the work place is carried out, establishing the noncompliance with the law in force and taking measures to ensure compliance with such laws.

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Statistics are drafted, referring to work accidents and professional illnesses caused by hazardous chemical substances.

Intervention teams in case of chemical accident with periodically instructed staff are organized at company level.

Authorized employees of the internal prevention and protection service perform the inspection of the work places according to the operational procedure.

The explosion protection document is elaborated according to Government Ordinance no. 1058/2006 for the following plants: Ammonia, Nitric Acid, and Ammonium Nitrate.

The equipment used in areas with danger of explosion is certified upon availability date.

Workers have access to personal instructions regarding the usage of dangerous chemical substances:

- The staff has individual protection equipment
- Measures of collective protection are ensured.

Collective protection measures for the source of risk – complex fertilizers NPK type

Technical Measures

Monitoring system of the main functioning parameters for the safety of the equipment (pressure, temperature, concentration, flow capacity, level etc), with acoustic and optical warning signals in case of malfunction.

Toxic gas, fire and explosion detectors

Protection devices – flange fenders on all the dangerous liquids layouts

Ammonia and nitric acid layouts painted in conventional colors

Signaling for work safety health and according to Government Ordinance no. 971/2006 (safety, warning, interdiction, obligation marks, delimitation of danger zones)

Ventilation systems.

Rescue showers for the danger of splashing with corrosive substances.

Water sources with upward jet (for washing the eyes in case of splashing)

Periodical ISCIR inspections of under-pressure equipment.

Toxic gases level control

Organization and provision of individual insulating protection equipment

Endowment and organization of medical help trained in case of gassing.

Administrative measures

Manufacturing regulation, work instructions regarding work safety and health and fire prevention.

Safety data sheets for hazardous substances.

Organization of an information system for surveillance and intervention:

- Action plan in case of fire
- Internal Emergency Plan (PUI).
- Evacuation action plan in emergency situations
- Action plan in case of earthquake
- Action plan for safe road transport (PSTR).

Authorization for the job position, employees in the production sector, maintenance, repair (mechanic, electric, automation) in technological installations.

Work safety and health training for Azomures employees, in all stages (upon hiring, at work, periodically, supplementary) and work safety and health instruction for the employees from the

companies that perform services based on contract and for the persons that are on the platform with the employer's permission, related to:

- risk of professional injury and illness at the work place
- minimal requests of health and safety of work, stipulated by legal regulations applicable to the specific activity at the work place
- tasks and responsibilities of the employees
- usage of work equipment and individual protection equipment
- prevention and protection measures, action plan in case of danger
- giving first aid to the injured at the work place

Risk management measures for human health

During ammonium nitrate manufacturing process, eyes might be exposed to dust in concentrations that cause irritations. If existing control measures are applied (technical control measures and personal protection equipment, based on the classification and labeling as H272 and H319), the substance is not hazardous for workers.

8.2.2 Personal protection measures, such as personal protection equipment

Technical measures: provide a ventilation system, where necessary.

Hygiene measures: do not eat, drink or smoke while handling the product. Wash hands after handling and before eating, smoking or using the toilet, as well as at the end of the working period.

(a) Respiratory protection:

Personal protection during production activities - breathing apparatus
- protective mask

(b) Hand protection:

Protective gloves (heat resistant).

(c) Eye protection:

Face protection equipment - tight safety goggles (plastic frame, polycarbonate lens) for chemical substances.

- face mask (polycarbonate) – in case of danger of nitrate splashes

(d) Skin protection:

Protective clothing:

Dust resistant overalls (breastplate duck overalls, coat);

Winter or summer shirt (natural fibers - duck);

Protective footwear:

Chemical and mechanical aggression resistant boots, with anti-static properties that allow usage in explosive environments (leather with rubber soles).

8.2.3 Environmental exposure control

Recommendations on personal protection apply for high levels of exposure.

Select the personal protection equipment depending on the type of risk.

Risk management measures for the environment

Due to the low toxicity of ammonium nitrate for aquatic organisms and its regulation by various European/national regulations, a risk and environmental exposure assessment is not considered necessary for ammonium nitrate.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES
9.1. Information concerning the main physical and chemical properties

a) Aspect of the substance/mixture

Physical state: granules

Color: white-gray

b) Odor: odorless

No.	Physical and chemical properties of the substance / mixture	Unit	Value for the substance /mixture	Remarks
c)	pH		>4.5	In solution of 100g/L
d)	Boiling point/ boiling temperature range	°C	>210	Decomposes before boiling
e)	Melting/ freezing point	°C		Depending on the composition; it may decompose before melting.
f)	Flammability	% vol.		Nonflammable (based on molecular structure).
i)	Vapor pressure	Pa	Negligible	At room temperature
j)	Surface tension			No surface activity (based on molecular structure).
k)	Water solubility	g/L		Soluble
l)	Partition coefficient n-octanol/water	Log Kow		Not necessary as the substance is inorganic.
m)	Viscosity	Cp		Testing method not applicable for solids; relevant for liquids.
n)	Auto-flammability	°C		Does not self-ignite.
o)	Explosive properties			Non explosive
p)	Oxidizing properties			No oxidizing properties
s)	Bulk density	kg/m ³	950 -1150	
t)	Stability in organic solvents and identity of the relevant decomposition products			Not necessary if the substance is inorganic.

9.2. Additional information

No available additional information.

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SECTION 10. STABILITY AND REACTIVITY

10.1. Reactivity

Complex fertilizers react with combustible substances (e.g. Diesel fuel, lubricants etc.) and incompatible materials: reducing agents, acids, bases, chlorates, chlorides, chromates, nitrites, permanganates, metallic powders.

10.2. Chemical stability

The product is stable in normal storage, handling and usage conditions.
In order to increase product stability, anti-caking agents are used.

Anti-caking - Additive of unknown composition

IUPAC name: additive of unknown composition

10.3. Hazardous reactions potential

If heated at very high temperatures, over 170 °C and over 200 °C, ammonium nitrate may cause an explosion at any moment, especially if contaminated with combustible substances, organic substances, coal, oil, or if ammonium nitrate is confined in closed spaces (pipes, containers, tankers with metallic walls).

The product is prone to chemical self-ignition when it comes into contact with readily oxidizing organic substances, finely divided metals, superphosphates.

10.4. Conditions to avoid

The product decomposes when heated. Avoid confined spaces.

10.5. Incompatible materials

Reducing agents, strong acids and bases, metallic powders, combustible materials, chromates, zinc, copper and its alloys, chlorates.

10.6. Hazardous decomposition products

Nitrogen oxides (NO, NO₂) released during ammonium nitrate decomposition are highly toxic.

SECTION 11. TOXICOLOGICAL INFORMATION

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Information in this section is derived from characterization of ammonium nitrate which is the constituent that gives danger sorts of NPK 26-13-0; 27-13,5-0; 26-5-5; 27-6-6.

Toxicokinetics (absorption, metabolism, distribution and elimination)

The results of the studies on absorption, metabolism, distribution and elimination:

Based on low MW, high water solubility, assumed low logPow high absorption is expected. However, the ion formation of the substance immediately when in contact with a fluid decreases the absorption. Therefore, 50% absorption is taken for oral, dermal and inhalation exposure

11.1. Information on toxicological effects

The relevant hazard classes for which information is provided are:

- (a) Acute toxicity
- (b) Skin corrosion / irritation
- (c) Eye irritation / damage
- (d) Sensitization of the skin or the respiratory system
- (e) Mutagenicity germ cell
- (f) Carcinogenicity
- (g) Toxicity for reproduction
- (h) STOT (specific target organs of toxicity) – unique exposure
- (i) STOT (specific target organs of toxicity) – repeated exposure
- (j) Aspiration hazard

11.1.1 Information for each hazard class

- (a) Acute toxicity - oral LD50 > 2000 mg/kg bw
 - dermal LD50 > 5000 mg/kg bw
 - inhalation LC50 > 88.8 mg/l
 - other routes – no available information

Ammonium nitrate does not have to be classified for acute oral, dermal or inhalation toxicity as all LD50/LC50 tested values exceed the highest value used for classification according to CLP Regulation.

Repeated dose toxicity

Oral 28 days - NOAEL \geq 1500 mg/kg bw/d (with potassium nitrate)

52 weeks - 256 mg/kg bw/d (with ammonium sulphate)

Inhalation 2 weeks - NOAEL \geq 185 mg/m³ air

Dermal – no available studies

Value used for CSA (oral route): NOAEL: 256 mg/kg bw/d (with ammonium sulphate)

Value used for CSA (route: inhalation): NOAEC \geq 185 mg/m³ (2 weeks)

Based on available data, ammonium nitrate is not classified according to CLP Regulation for repeated dose toxicity.

(b) Skin corrosion/irritation

Ammonium nitrate does not cause skin irritations and is not corrosive.

(c) Serious eye damage / irritation

Ammonium nitrate is irritating for the eyes.

(d) Sensitizing of the airways and skin

No available data on sensitization of the respiratory system.

Ammonium nitrate is not classified according to CLP Regulation for skin sensitization.

Value used for CSA: not sensitizing for the skin

Value used for CSA: not sensitizing for the respiratory system.

(e) Mutagenicity

Based on the results of in vivo and in vitro studies, ammonium nitrate is not considered genotoxic.

Value used for CSA: genetic toxicity: negative.

(f) Carcinogenicity

Not carcinogen (tests using ammonium sulphate).

(g) Toxicity for reproduction

Oral 28 days - NOAEL \geq 1500 mg/kg bw/d (with potassium nitrate)

Ammonium nitrate is not classified according to CLP Regulation with regard to reproduction and developmental toxicity.

(h) STOT (specific target organs of toxicity) – unique exposure - conclusive but not sufficient for classification

(i) STOT (specific target organs of toxicity) – repeated exposure - conclusive but not sufficient for classification

(j) Aspiration hazard - there is no data available

11.1.2 The data in this subsection apply to the ammonium nitrate in the form under which it is placed on the market – no data available.

11.1.3 The results of experimental studies by route of exposure:

The acute toxicity after oral administration – the studies were conducted on rats and mice.

For rat: LD50: 2950 mg/kg – key study; experimental result

LD50: 2800 mg/kg, LD50: 2462 mg/kg, LD50: 4500 mg/kg supporting studies

For mouse: LD50: 2085 mg/kg – supporting studies; experimental result

The acute toxicity after administration by inhalation - the studies were conducted on rats.

LC50: > 88,8 mg/L - supporting studies; experimental result

The acute toxicity after dermal administration - the studies were conducted on rats.

LD50: > 5000 mg/kg

Ammonium nitrate must not be classified for acute oral toxicity, dermal and inhalation toxicity, because all the values used for the LD50/LC50 tests are more than the highest value that is used in the classification of the CLP Regulation.

11.1.4 For the following hazard classes: STOT – single exposure, STOT – repeated exposure, aspiration hazard – conclusive but not sufficient for classification.

11.1.5 Information on the likely routes of exposure

The likely routes of exposure are ingestion (swallowing), inhalation or skin / eyes exposure - there are no known health effects.

11.1.6 Symptoms related to the physical, chemical and toxicological characteristics

No data available.

11.1.7 The known delayed and immediate effects and the chronic effects of long term exposure and short term exposure

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The toxicological tests were made on rats, tests for skin irritation / eyes, the respiratory tract were made on rabbits.

There is no conclusive data on the effects of delayed or chronic of long term or short-term exposure.

11.1.8 Interactive effects

No data available.

11.1.9 Absence of specific data

No data available.

SECTION 12.	ECOLOGICAL INFORMATION
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12.1. Toxicity

Aquatic compartment (including sediments)

Toxicity data

The main toxic component in ammonium salts is ammonia. Recent assessments concerning ammonia toxicity show that both ionized and un-ionized forms are toxic.

For this reason a common toxicity model is proposed, in which ammonia is more toxic at elevated pH values and ammonium ion contributes to toxicity at lower pH values.

Short-term toxicity for fish

Values used for CSA: LC50 for static water fish: 447 mg/L (at 48 hours).

Long-term toxicity for fish

No data available.

Short-term toxicity for aquatic invertebrates

Values used for CSA: EC50/LC50 for fresh water invertebrates: 490 mg/L

Long-term toxicity for aquatic invertebrates

There are no available long-term studies for aquatic invertebrates.

Algae and aquatic plants

Value used for CSA: EC50/LC50 for fresh water algae: >1700 mg/L

NOEC for fresh water algae: 1700 mg/L

Sediment organisms

The chemical safety assessment does not indicate the need for a study concerning the effects on sediment organisms.

Other aquatic organisms

No available information.

PNEC derivation - PNEC aqua (fresh water): 0.45 mg/L

PNEC aqua (marine water): 0.045 mg/L

PNEC aqua (intermittent releases): 4.5 mg/L

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PNEC in sediments - PNEC values for sediments should be calculated using the equilibrium partitioning method (EPM) in EUSES, by using the PNEC aqua and the log Kow. For inorganic substances the PNEC value cannot be derived.

Due to the low toxicity of ammonium nitrate for aquatic organisms and its regulation by different European/national laws, the hazard and environmental exposure assessment is not considered necessary.

Terrestrial compartment - studies scientifically unjustified.

Atmospheric compartment - no available data.

Microbiological activity in STP

Toxicity for aquatic micro-organisms

Value used for CSA: EC50/LC50 for aquatic micro-organisms: >1000 mg/L

NOEC aquatic micro-organisms: 180 mg/L

PNEC for STP: 18 mg/L

The Urban Wastewater Directive (1991) sets standards for the collection and treatment of wastewater from homes and some industrial sectors.

12.2. Persistence and degradability

Abiotic degradability

Ammonium nitrate completely dissociates in water. No additional information is requested/available.

Biotic degradability

Studies are not necessary as the substance is inorganic. The biodegradation rate in wastewater treatment plants is of 52 g N/kg dissolved solid/day at 20 °C.

In the anaerobic transformation of nitrate into N₂, N₂O and NH₃, the biodegradation rate in wastewater plant at 20 °C is 70 g N/kg dissolved solid/day at 20 °C.

Hydrolysis - ammonium nitrate is completely dissociated into ions in water: NH₄⁺ and NO₃⁻. Therefore, testing is considered not necessary.

Photolysis - in air, water, soil - no available data

Biodegradation - inorganic substances are not biodegradable (based on chemical properties).

12.3. Potential for bioaccumulation

The partition coefficient octanol - water (Kow): not relevant as the substance is inorganic, but it is considered low (based on high water solubility).

The bioconcentration factor (BCF) - low potential for bioaccumulation (based on substance's properties).

12.4. Mobility in soil

Adsorption/desorption

Adsorption coefficient - low potential for adsorption (based on substance's properties).

Volatilization - no available data.

Distribution modeling - no available data.

12.5. PBT and vPvB assessment results

In accordance with Annex XIII of the EC Regulation no. 1907/2006, PBT and vPvB assessments have not been conducted as ammonium nitrate is inorganic.

12.6. Other adverse effects

There is no information concerning other adverse effects on the environment.

SECTION 13. DISPOSAL CONSIDERATIONS

13.1. Waste treatment methods

Disposal methods

Wastes must be disposed of in compliance with national and local regulations. Controlled biodegradation in wastewater treatment is possible.

Relevant provisions of the harmonized EU legislation and domestic legislation regarding waste.

National legislation in force:

Law no. 211/2011 concerning wastes treatment.

Law no. 265/2006 – The Law on environment protection.

Law no. 249/2015 related to the packaging and waste packaging management.

GD no. 856/2002 - The evidence of wastes management, with subsequent modifications.

Law on labor security and health no. 319/2006, GD no. 1425/2006 on approving the Methodological Norms for the enforcement of the provisions set by the Law on labor security and health no. 319/2006, GD no.355/2007 on the surveillance of workers' health with subsequent modifications.

Decision no. 1061/2008 on transport of hazardous or non-hazardous wastes on Romanian territory, with subsequent modifications.

UE Legislation in force:

Regulation (EC) no. 1907/2006 of the European Parliament and of the Council regarding the Registration, evaluation authorization and restriction of chemicals (REACH).

Regulation (EC) no. 1272/2008 of the European Parliament and of the Council on the classification, labeling and packaging of substances and mixtures.

European Agreement concerning the International Carriage of Dangerous Goods by Road (ADR).

European Agreement concerning the International Carriage of Dangerous Goods by Rail (RID).

SECTION 14. TRANSPORT INFORMATION

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Information concerning classification for:

Road transportation (ADR):

NPK complex fertilizers type: **26-13-0; 27-13.5-0; 26-5-5; 27-6-6**

14.1. UN number: 2067

14.2. UN name for dispatch: FERTILIZERS CONTAINING AMMONIUM NITRATE

14.3. Transportation hazard class (classes): hazard class 5.1 - oxidizing substances O2 (solids), hazard identification no. 50 label 5.1

14.4. Packaging group: Group III

Special provisions – Loading, unloading, handling – CV24

Bulk - AP6, AP7, VC1, VC2

Transport category / tunnel restriction code – 3 (E)

Rail transportation (RID):

14.1. UN number: 2067

14.2. UN name for dispatch: FERTILIZERS CONTAINING AMMONIUM NITRATE

14.3. Transportation hazard class (classes): hazard class 5.1 - oxidizing substances O2 (solids), hazard identification no. 50 label 5.1, NHM code 310230,

14.4. Packaging group: Group III

Packaging instructions: P002, IBC08, LP02, R001

Special packaging provisions: B3

Special provisions – Loading, unloading and handling – CW24

Bulk – AP6, AP7, VC1, VC2

Transport category - 3

Marine transportation (IMDG/IMO Code):

14.1. UN number: 2067

14.2. UN name for dispatch: FERTILIZERS CONTAINING AMMONIUM NITRATE

14.3. Transportation hazard class (classes): hazard class 5.1, label 5.1

EmS Fire - F-H

EmS Spiel- S-Q

14.4. Packaging group: Group III

Special provisions - Stacking: category A

14.5. Environmental hazards

According to the criteria of the IMDG Code, ammonium nitrate is not pollutant for the environment and marine aquatic compartment.

14.6. Special precautions for users

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Transportation of NK, NP or NPK complex fertilizers, with a higher ammonium nitrate content of 70% (ex.: 26-13-0; 27-13,5-0; 26-5-5; 27-6-6) is done according to the legislation in use for hazardous substances. RID, ADR and IMDG provisions shall be respected. Transportation and storage of the product is carried out at temperatures between -10 and +30 °C. Transportation means must be clean, dry and covered with waterproof covers, free of sharp edges that might cut or rip the bags. The product may also be transported in bulk, covered with a waterproof, nonflammable cover, or in TALS metallic wagons.

In case of bulk deliveries on sea, the ship storage areas must be clean and dry (they must not be contaminated with oil (grease), residues from previous transports). The walls must be free of detachable rust. The walls must not be covered with paper.

The product is packed in polyethylene bags or double bags (polyethylene and polypropylene). Polyethylene bags are closed by welding, plying or sewing together with polypropylene bags and the polypropylene bags are closed by sewing.

Each delivery is accompanied by the Conformity Statement. At the client's request, the product is accompanied by a Test Report.

Vehicles which transport packages (bags) with fertilizers containing ammonium nitrate (complex fertilizers NPK type 26-13-0; 27-13.5-0; 26-5-5; 27-6-6) should be signaled by applying **2** rectangular reflective **orange plates** (front and back), which indicate on the top hazard identification number and on the bottom UN number specific for dangerous substance, of dimensions specified in legislation in use (ADR), labeled so that in case of fire the markings must remain legible for at least 15 minutes (see figure 1).

For NPK complex fertilizers sorts 26-13-0; 27-13.5-0; 26-5-5; 27-6-6, for completing signaled plates will be applied **label plate**, exposed to view on the sides and in the back of the vehicle applied in such a manner that it cannot be removed, in this case **oxidizing** substances – conventional sign – flame over a black circle on a yellow background, the symbol "5.1" in the lower corner – figure 2.

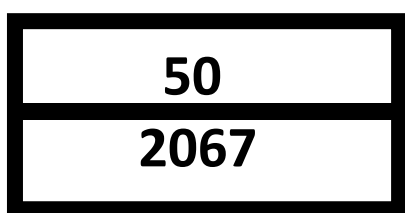


fig. 1



fig. 2

According to the provisions of EC Regulation no. 1272/2008, package labels will include the following legible specifications: substance name, producer's full name and address, nominal weight, product identifiers, hazard symbols, warnings, hazard statements (H), precautionary statements (P). All transports will be accompanied by the transport documents appropriate for transported goods, according to the legislation in use.

14.7. Bulk transport, according to Annex II to MARPOL convention and IBC Code

Not applicable.

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SECTION 15.	REGULATORY INFORMATION
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15.1. Safety, health and environmental regulations/legislation specific for the substance/mixture
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Relevant information regarding the domestic legislation

Law on labor security and health no. 319/2006, GD no. 1425/2006 on approving the Methodological Norms for the enforcement of the provisions set by the Law on labor security and health no. 319/2006, GD no. 355/2007 on the surveillance of workers' health with subsequent modifications.

Law no. 265/2006 for the amendment of GEO no. 195/2005 on environment protection

Decision no. 1391/2006 for the approval of the Regulation concerning the application of Government Emergency Ordinance no. 195/2002 regarding traffic on public roads, with subsequent amendments and supplements.

ISCIR technical prescriptions in use.

Order no. 2737/17.12.2012 regarding the approval of the Procedure concerning the designation of the bodies in charge with the issuance of the aggregation certificates and of the prototype conformity certificates according to the European Agreement concerning the International Carriage of Dangerous Goods by Road (ADR), as well as with the inspection for the certification for maintaining the exploitation conformities for the specialized superstructures installed on the road vehicles for the carriage of dangerous goods and of packaging of dangerous goods transported on the road.

Law no. 59/2016 referring to the control of hazards in case of serious accidents involving dangerous substances.

Decision no. 1175/2007 for the approval of the Norms referring to the performance of road transportation activities for dangerous goods in Romania.

Law no. 360/2003 on dangerous substances and preparations republished in 12.03.2014.

Law no. 278/2013 on industrial emissions.

Relevant information regarding the EU legislation

Regulation (EC) no. 1907/2006 of the European Parliament and of the Council regarding the Registration, evaluation authorization and restriction of chemicals (REACH).

Regulation (EC) no. 1272/2008 of the European Parliament and of the Council on the classification, labeling and packaging of substances and mixtures.

Regulation (EU) no. 286/2011 by the Commission from 10.03.2011 amending Regulation (EC) no. 1272/2008.

Regulation (EC) no. 830/2015 of the Commission from date of 28.05.2015 amending Regulation (EC) no. 1907/2006.

Directive no. 2012/18/UE of the European Parliament and of the Council from 4.07.2012 on the control of major-accident hazards including dangerous substances (SEVESO III).

Regulation (EU) No 98/2013 of the European Parliament and of the Council of 15 January 2013 on the marketing and use of explosives precursors.

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EC no. 2003/2003 regulation of the European Parliament regarding fertilizers with its subsequent amendments relating to EN standards drawn up by the European Committee for Standardization. European Agreement concerning the International Carriage of Dangerous Goods by Road (ADR), 2017 edition.

Regulation referring to the International Carriage of Dangerous Goods by Rail (RID), 2017 edition
 International Maritime Dangerous Goods (IMDG), 2017 edition.

15.2 Chemical safety assessment

A chemical safety assessment (CSA) was conducted and a chemical safety report (CSR) was elaborated for ammonium nitrate which makes the NPK sorts 26-13-0; 27-13.5-0; 26-5-5; 27-6-6 hazardous during transportation.

SECTION 16. ADDITIONAL INFORMATION

a) A clear evidence of added, deleted or modified information

Version (edition, revision) number	Date	Page number	Evolution of the information
edition 7 revision 0	12.02.2013	2, 3, 16, 17,18, 20	At page 2 section 2, chapter 2.1 were introduced the NPK sorts 20-5-15 and 21-5-16. At page 3 it was added the warning word:attention and an intervention phrase, at section 2 chapter 2.2, elements for label. At page16,section 14, chapter 14.6.1 were introduced the NPK sorts 20-5-15 and 21-5-16. At page 17 section 14, chapter 14.6.2 it was mentioned the type of warning panels which are put up on vehicles, if transports packages (bags) or goods in bulk. At page 18 section 15, chapter 15.1, at page 20 section 16 b) and c) it was modified the ADR and RID edition number.
edition 7 revision 1	12.09.2013	2, 16	At page 2 section 2, chapter 2.1 and page 16 section 14, chapter 14.6.1 were introduced the NPK sorts

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			21-7-12 and 21-7-13
edition 8 revision 0	20.11.2013	10, 18	At page 10, chapter 8.2.1. – Organizational measures, Monitoring and intervention plans were modified At page 18 section 15.1 – information regarding national legislation was modified
version 9	28.11.2014	2, 4, 12, 16	At page 2, section 2, chapter 2.1 and page 16, section 14, chapter 14.6.1 were taken several sorts of NPK and have made changes to some sorts with potassium sulphate. At page 4, section 3, chapter 3.1 at ammonium nitrate composition changed typical concentration. At page 12, section 10, chapter 10.2 at conditioning agents was added dolomite.
version 10	14.01.2015	7	At page 7, section 7, chapter 7.2 was modified the number of rows it is stored bags.
version 11	01.06.2015	1, 2, 15, 16	At page 1, section 1.4 emergency telephone number was modified. At page 2, section 2.1 it was removed classification in accordance with directive 67/548/ EEC. At page 15, chapter 13.1 - Waste treatment methods national legislation was modified. At page 16, section 14 they were added special provisions for carriage.
version 12	01.02.2016	2, 7, 14, 19-20	At page 2, section 2, chapter 2.1 were introduced the NPK new sorts. At page 7, section 7, chapter 7.2 they were also completed on the storage. At page 14, section 1, they have introduced additional toxicological data. At page 19-20 section 15.1 it was introduced Law 360/2003 republished and Regulation no.830/2015.
version 13	09.05.2016	7, 20	At page 7, section 7.2 it was rephrased the provision referring to stacking storage.
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			At page 20, section 15 the legislation was amended SEVESO.
version 14	11.11.2016	2	At page 2, section 2, chapter 2.1 it has introduced the NPK new sort.
version 15	20.02.2017	17, 18, 20	At page 17, in chapter 14.4 was introduced transport category / tunnel code. At page 18, chapter 14.6 it changed the name of the hazard labels in label places, according to ADR 2017. At page 20, chapter 15.1 it changed the edition number ADR, RID, IMDG
version 16	26.04.2017		Non-hazardous NPK sorts of transport were removed from the SDS content.
version 17	13.03.2018	2, 21	At page 2, section 2, chapter 2.1 and and on page 21, section 14.6, the phrases concerning the hazard of the sorts were reworded.

b) List of abbreviations and acronyms used throughout the Safety Data Sheet

SDS	- Safety Data Sheet
ECHA	- European Chemicals Agency
EC	- European Commission
ESIS	- European Chemical Substances Information System
(FE) EFMA	- Fertilizers Europe (European Fertilizer Manufacturers Association)
REACH	- EC Regulation No. 1907/2006 of the European Parliament and Council concerning the registration, evaluation, authorization and restriction of chemical substances
CSR	- Chemical Safety Report
CSA	- Chemical Safety Assessment
ES	- Exposure Scenario
DNEL	- Derived no effect level
DMEL	- Derived minimal effect level
PNEC	- Predicted No Effect Concentration
BCF	- Bioconcentration factor
NOAEL	- No observed adverse effect level
NOAEC	- No Observed Adverse Effects Concentration
ECETOC	- European Center for Ecotoxicology and Toxicology of Chemicals
EUSES	- The European Union System for the Evaluation of Substances
STP	- Sewage Treatment Plant

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EC50	- Concentration of toxic material for which 50% of the tested organisms survive
LD50	- Lethal dose for 50% of the tested population
LC50	- Lethal concentration for 50% of the tested population
STOT	- Specific target organ toxicity
PBT	- Persistent, Bioaccumulative, Toxic
vPvB	- very Persistent, very Bioaccumulative
MRR	- Measures of risk reduction
UN	- United Nations
SEVESO III	- European Council Directive no. 2012/18/UE of July 4, 2012 on the control of major-accident hazards involving dangerous substances
ISCIR	- State Inspection for the Control of Boilers, Under-Pressure Vessels and Lifting Devices
ACGIH	- American Conference of Governmental Industrial Hygienists
ADR	- European Agreement referring to the International Carriage of Dangerous Goods by Road, 2017 edition.
RID	- Regulation referring to the International Carriage of Dangerous Goods by Rail (RID), 2017 edition.
IMDG	- Regulations referring to the maritime transportation of hazardous substances (IMDG), 2017 edition.
MARPOL	- International Convention for the Prevention of Pollution From Ships
IBC	- International Code for the Construction Equipment of Ships Carrying Dangerous Chemicals in Bulk
GESTIS	- Information system on hazardous substances of the German Social Accident Insurance
w/w	- mass unit
b/w	- body weight

c) Bibliography

GESTIS Database - Material Safety Data Sheets

Amuliu Proca, Gabriel Stănescu - Substanțe și produse utilizate în industria chimică-pericol de incendiu - pericol de explozie – toxicitate (Substances and products used in the chemical industry-fire hazard-explosion hazard-toxicity), 1984

Studies according to the Chemical Safety Report

Guidance on safe use – The joint/individual ECHA Registration file for the substance

Official Journal of the European Union – EU Regulation no. 830/2015 of the European Council of 28.05.2015

EFMA - Guidance for the Compilation of Safety Data Sheets for Fertilizer Materials.

ESIS - European Chemical Substances Information System

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Official Journal of the European Union – EC Regulation no. 1907/2006 of the European Parliament and Council concerning the registration, evaluation, authorization and restriction of chemical substances (REACH)

ADR - European Agreement referring to the International Carriage of Dangerous Goods by Road, 2017 edition

RID - Regulation referring to the International Carriage of Dangerous Goods by Rail (RID), 2017 edition

IMDG - Regulations referring to the maritime transportation of hazardous substances, 2017 edition

Relevant hazard statements / Relevant precautionary phrases

H 272 – May intensify fire; oxidizer

H 319 – Causes serious eye irritation

Precautionary statements: Prevention

P210 – Keep away from heat/sparks/open flames/hot surfaces. No smoking.

P220 – Keep/Store away from clothing/combustible materials (lubricants, Diesel fuel, oil, paints etc.)

P 264 – Wash hands thoroughly after handling

P 280 – Wear protective gloves (heat resistant)/protective clothing (powder resistant overalls)/tight safety goggles/ face mask

Intervention

P 370 + P 378 – In case of fire use plenty of water (flooding). Use dust or carbon dioxide extinguishers for cooling;

P 305+351+338 – If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

P 337+ P313 – if irritation persists see the doctor.

Note:

The information included in this safety data sheet is based on the data available at the time of publication.

The client and the user assume all risks regarding usage, handling and storage of this product.

There are no guarantees for the product in case of improper handling, transport and storage of the product, not complying with the specifications of the Technical Specification and the Safety Data Sheet.

EXPOSURE ASSESSMENT

Under the REACH Regulation a chemical safety assessment (CSA) for the whole life-cycle of a substance is required. The CSA describes how the manufacturer controls, or recommends downstream users to control, exposures of humans and the environment.

Human exposure assessment

A qualitative assessment has been performed since the leading toxicological effect is a local endpoint (eye irritation). For this endpoint no dose-effect response curve can be determined and therefore a DNEL cannot be derived. However, DNELs are derived for systemic toxicity for workers and the general population but are not assessed against exposure estimates. A quantitative assessment for systemic toxicity is not considered relevant for this substance as it did not show any systemic effects in an subacute toxicity study for an analogue (potassium nitrate, tested up to 1500 mg/kg bw/day) and only minor effects in studies conducted with the analogue ammonium sulfate: 90 days oral subchronic toxicity study and 2 years oral chronic toxicity study which revealed NOAELs of 886 mg/kg bw/day and 256 mg/kg bw/day, respectively. These effects are noted at levels that humans are normally not exposed to.

Furthermore, ammonium nitrate was assessed within the OECD HPV program (SIAM 25) as part of the nitrates category and concluded to be of low priority for further work for human health.

Environmental exposure assessment

An environmental exposure and risk assessment has not been performed. Although ammonium nitrate belongs to the nitrate category it has to be mentioned that ammonium nitrate can act different compared to the other nitrate compounds due to the ammonium cation:

In aqueous solution, ammonium salts are completely dissociated into NH_4^+ and a corresponding anion. This equilibrium depends on temperature, pH and ionic strength of the water in the environment. Un-ionized NH_3 species exists in the aquatic environments and the fraction $(\text{NH}_3 / (\text{NH}_3 + \text{NH}_4^+))$ steeply increases with elevated pH value or temperature. It is well known that toxicity to aquatic organisms has been attributed to un-ionized ammonia (NH_3) species, and NH_4^+ species is considered to be non- or significantly less-toxic (Emerson et al., 1975). However, recent developments in assessing ammonia toxicity clearly show that in contrast to earlier assumptions where un-ionized ammonia was considered to be the toxic component, both the uncharged and charged molecule are toxic. Therefore, a joint toxicity model has been proposed, with ammonia causing most toxicity at high pH values and ammonium ion also contributing to toxicity at lower pH values (U.S. EPA 1999, OECD 2007).

It is generally accepted, that the principal toxic component of ammonium salts such as ammonium nitrate, -sulphate or -chloride is ammonia, rather than the corresponding anion (see also: OECD2004, SIDS ammonium chloride or OECD 2007 ammonium sulphate). Therefore toxicity values for ammonium salts (such as: ammonium -sulphates, phosphates, carbonates, chlorides or nitrates), where the major toxic component is ammonia, can be considered as equivalent. Consequently, this hazard assessment comprises the total topic of ammonia toxicity.

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U.S. EPA (1999) published an excellent review on Ammonia toxicity, with special consideration on the pH- and temperature dependence. A huge amount of studies is available on Ammonia toxicity, however a comparability of these toxicity data is difficult, since various temperature- and pH conditions were present during testing. U.S. EPA (1999) re-evaluated existing data on Ammonia toxicity by adjusting toxicity values to definite temperature and pH- conditions and by thereby allowing comparability.

Study results of the group of the following nitrates were evaluated: ammonium nitrate, calcium nitrate, calcium nitrate double salt, magnesium nitrate, Nitcal-K, potassium nitrate and sodium nitrate.

All nitrates show a low or negligible toxicity to vertebrates, invertebrates and algae. Although results of the studies and publications are sometimes expressed as being > 100 mg/L, lowest measured value without effects is 447 mg/L (study with fish on ammonium nitrate).

Ammonium nitrate has been evaluated within the OECD HPV program (SIAM 25) as part of the nitrates category. It was concluded that all substances within this category are of low priority for further work due to their low hazard profile. The substance does not hydrolyze nor is there evidence for photodegradation. In aqueous solution, it is completely dissociated into nitrate (NO₃⁻) and the corresponding cation. Due to the inorganic nature of the substance standard biodegradation testing systems are not applicable.

Nitrification and de-nitrification processes occur naturally in streams and rivers, as well as in many secondary sewage treatment processes. Based on the high water solubility and the ionic nature, the substance is not expected to adsorb or bioaccumulate to a significant extent. Based on the physico-chemical properties, water is expected to be the main target compartment.

Nitrate substances are known to play an important role in the nutrient enrichment of surface waters, commonly called eutrophication. Eutrophication waters are characterized by an elevated nutrient concentrations, which stimulate the growth of certain algal species, favoring simple algae and plankton growths. The oxygen concentration in water will generally decrease influencing other lives, such as most fish species leading to a negative effect on the biodiversity of the ecosystem. As eutrophication is a common effect due to an excess in nitrate in the environment, the problem is covered in European Regulations.

The Directive 2000/60 of the European parliament and of the council of 23 October 2000 establishing a framework for Community action in the field of water policy and the Council Directive 91/676/EEC of 12 December 1991 concerning the protection of waters against pollution caused by nitrates from agricultural sources are both important European Regulations regulating the emission and concentration of nitrate substances in the environment.

The Nitrates Directive (1991) aims to protect water quality across Europe by preventing nitrates from agricultural sources polluting ground and surface waters and by promoting the use of good farming practices. The Nitrates Directive has close links with other EU policies concerning water, air, climate change and agriculture, and its implementation yields benefits in all these areas:

- Reducing nitrates is an integral part of the Water Framework Directive (2000), which establishes a comprehensive, cross-border approach to water protection organised around river basin districts (RBDs), with the aim of achieving good status for European bodies of water by 2015.

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- The new Groundwater Directive (2006) confirms that nitrate concentrations must not exceed the trigger value of 50mg/l. Several Member States have set their own tighter limits, in order to reach good status.
- Air and soil quality: livestock management and farming cause, among other things, emissions of ammonia (NH₃), which have an impact on human health and on the environment, as they contribute to the acidification process in soil, eutrophication of waters and ground-level ozone pollution, together with other pollutants (sulphur dioxide, nitrogen oxides, volatile organic compounds). The full implementation of the Nitrates Directive is expected to contribute to the reduction of ammonia emissions by 14% on 2000 levels by 2020, as measures limiting, for example, amounts of fertiliser applied, have a positive impact on both nitrate losses towards waters and ammonia emissions into the air.
- Climate change: All activities related to livestock and fertiliser management release nitrous oxide (N₂O) and methane (CH₄), greenhouse gasses with a global warming potential 310 and 21 times higher than CO₂ respectively. If fully implemented, the Nitrates Directive could cut N₂O emissions by 6% on 2000 levels by 2020, for example, and contribute to climate change mitigation.
- The common agricultural policy (CAP) backs up the Nitrates Directive through direct support and rural development measures. For example, several Member States have included nutrient management measures, such as wider buffer strips around water courses, among the agri-environmental initiatives for which farmers can receive payments. Direct support is subject to crosscompliance with EU environmental legislation, including the Nitrates Directive.
- The Urban Wastewater Directive (1991) sets standards for the collection and treatment of wastewater from homes and some industrial sectors.

Because of the low toxicity of ammonium nitrate towards aquatic organisms and regulation within several European/National Laws an environmental exposure and risk assessment for ammonium nitrate is not considered necessary.

Ammonium nitrate is mainly used in fertilizers, but besides that is also a constituent in several preparations and materials. The qualitative assessment will focus on the manufacturing of fertilizers, use by professionals and consumers. Furthermore the non-fertilizer uses will also be assessed. In table 1 the uses that have been further assessed are summarized.

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Table 1. Short description of all identified uses with their use descriptors and life cycle stage

Number (IU)	Short description of identified use	Product Category (PC)	Life Cycle Stage(s) covered by the IU						Sector of use (SU)	Process Category (Proc)	Article Category (AC)	Environmental Release Category (ERC)
			Manufacture	Formulation	End Use			Service Life (for article)				
					Industrial	Professional	Consumer					
1	Manufacturing of the substance, including handling, storage and q control	-	X						SU8, 9	PROC2, PROC3, PROC1, PROC8a, PROC8b, PROC9,	-	ERC1
2	Sampling, loading, filling, transfer, dumping, bagging of substance (charging/discharching) at non-dedicated facilities. Industrial/professional setting.	-		X	X	X			SU3, 22	PROC8a	-	ERC2, ERC6a, ERC8b, ERC8e

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Number (IU)	Short description of identified use	Product Category (PC)	Life Cycle Stage(s) covered by the IU						Sector of use (SU)	Process Category (Proc)	Article Category (AC)	Environmental Release Category (ERC)
			Manufacture	Formulation	End Use			Service Life (for article)				
					Industrial	Professional	Consumer					
3	Sampling, loading, filling, transfer, dumping, bagging of substance (charging/discharging) at dedicated facilities. Industrial/professional setting.	-		X	X	X			SU3, 22	PROC8b	-	ERC2, ERC6a, ERC8b, ERC8e
4	Storage	-		X	X	X			SU3, 22	PROC1	-	ERC2, ERC6a, ERC8b,
5	Transfer of substance into small containers (dedicated filling line, including weighing). Industrial/professional setting.	-		X	X	X			SU3, 22	PROC9		ERC2, ERC6a, ERC8b,
6	Q control	-		X	X	X			SU3, 22	PROC15	-	ERC2, ERC6a,

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Number (IU)	Short description of identified use	Product Category (PC)	Life Cycle Stage(s) covered by the IU					Sector of use (SU)	Process Category (Proc)	Article Category (AC)	Environmental Release Category (ERC)	
			Manufacture	Formulation	End Use							Service Life (for article)
					Industrial	Professional	Consumer					
7	Use of ammonium nitrate in the manufacturing of formulations for adhesives and sealants, explosives, fertilizers and water treatment chemicals.	PC1, PC11, PC12, PC37		X				SU3, 10	PROC3, PROC5	-	ERC2	
8	Treating or coating of seed with fertilizer containing ammonium nitrate	PC12		X				SU10	PROC13	-	ERC2	
9	Use of ammonium nitrate as an intermediate to synthesise other substances	PC19			X			SU3	PROC2, PROC3	-	ERC6A	
10	Professional use of fertilizers containing ammonium nitrate - liquid fertigation at open field (non industrial spraying)	PC12				X		SU22	PROC11		ERC8E	

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Number (IU)	Short description of identified use	Product Category (PC)	Life Cycle Stage(s) covered by the IU						Sector of use (SU)	Process Category (Proc)	Article Category (AC)	Environmental Release Category (ERC)
			Manufacture	Formulation	End Use			Service Life (for article)				
					Industrial	Professional	Consumer					
11	Professional use of fertilizers containing ammonium nitrate - liquid fertigation in the soil	PC12				X			SU22	PROC2	-	ERC8E
12	Professional use of fertilizers containing ammonium nitrate - fertigation at open field	PC12				X			SU22	PROC8A	-	ERC8E
13	Professional use of fertilizers containing ammonium nitrate - outdoor mixing	PC12				X			SU22	PROC19	-	ERC8E
14	Professional use of fertilizers containing ammonium nitrate - indoor mixing	PC12				X			SU22	PROC19	-	ERC8B
15	Professional use of fertilizers containing ammonium nitrate - greenhouse liquid fertigation in the soil	PC12				X			SU22	PROC2	-	ERC8B

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Number (IU)	Short description of identified use	Product Category (PC)	Life Cycle Stage(s) covered by the IU					Sector of use (SU)	Process Category (Proc)	Article Category (AC)	Environmental Release Category (ERC)	
			Manufacture	Formulation	End Use							Service Life (for article)
					Industrial	Professional	Consumer					
16	Professional use of fertilizers containing ammonium nitrate - greenhouse liquid fertigation (non industrial spraying)	PC12				X		SU22	PROC11	-	ERC8B	
17	Consumer end use - fertilization at open field	PC12					X	SU21		-	ERC8E	
18	Consumer end use - indoor use of fertilizers	PC12					X	SU21		-	ERC8B	
19	Consumer end use - matches and fireworks	PC11					X	SU21		-	ERC10A	

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Table 1, as it is proposed above, contains the identified uses. It also contains all the information necessary for a Tier 1 exposure assessment with ECETOC TRA (workers and consumers). However, as explained in the introduction a qualitative assessment will be performed for man, as the leading effect is eye irritation from which no dose-response curve can be established and a DNEL cannot be set. Normally the information from table 46 is used to derive a table listing the target group template needed to build the exposure scenarios based on the Tier 1 method: for worker (PROC driver of Tier 1 exposure estimate) and for consumer (PC or AC driver of Tier 1 exposure estimate). In this table IUs with the same driver of exposure/release would be grouped. However, as in this case a qualitative assessment will be done the reported uses will be grouped into the main sector of uses as the applicable RMMs will be comparable for all processes within a specific sector. The following exposure scenarios will be described:

Table 2. Overview on exposure scenarios and corresponding use descriptors

Exposure scenario	Short description of ES	Linked to IU	PC	SU	PROC	AC	ERC
ES1	manufacturing	1	-	8, 9	1, 2, 3, 8a, 8b, 9, 14, 15	-	1
ES2	industrial use including distribution and other activities related to the processes in industrial settings	2, 3, 4, 5, 6, 7, 8, 9	1, 11, 12, 19, 37	3, 10	1, 2, 3, 5, 8a, 8b, 9, 13, 15,	-	2, 6a
ES3	professional end use	2, 3, 4, 5, 6, 10, 11, 12, 13, 14, 15, 16	12	22	1, 2, 8a, 8b, 9, 11, 15, 19	-	8b, 8e
ES4	consumer end use	17, 18, 19	11, 12	21	-	-	8b, 8e, 10a

1. Manufacturing of the substance
1.1. Exposure scenario
1.1.1. Description of activities and processes covered in the exposure scenario

Manufacturing of the substance including handling, storage and q control: SU8/9, PROC1/2/3/8a/8b/9/14/15, ERC1

1.1.2. Control of workers exposure
Table 3. Worst case operational conditions and risk management measures

Frequency and duration of use			
	Value	Unit	Remarks
Duration of worker exposure	> 4	hours/day	
Product characteristics			
Physical state of the substance/product	Solid	solid/liquid	
Volatility of the substance/product	low	hPa	volatility of the substance
Relative molecular weight of the substance	80.04		Needed to calculate from ppm to mg/m ³
Concentration of substance in product	-	%	Not relevant
Operational conditions not accessible for risk management			
Is the activity performed inside or outside?	Inside		
Conditions and measures at process level (source) to prevent/limit release/exposure			
Conditions and measures related to control of dispersion towards the worker			
Is local exhaust ventilation needed?	No		
Conditions and measures related to personal protective equipment and hygiene			
Is respiratory protection needed?	No		
Is skin protection needed?	No		

According to CLP ammonium nitrate is classified as oxidizer H272 and irritating to eyes H319. Exposure of the eye to dust at concentrations leading to irritation during manufacturing of ammonium nitrate can occur.

1.1.3. Risk management measures

The risk management measures related to workers can be found in Table 4. Because ammonium nitrate is irritating to eyes, the risk management measures for human health aim to avoid direct contact with the substance.

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Table 4. Risk management measures related to workers at industrial sites

Information type	Data field	Explanation
Containment and local exhaust ventilation		
Containment plus good work practice required	Containment as appropriate	
Local exhaust ventilation required plus good work practise	Good standard of general ventilation	
Personal protective equipment (PPE)		
Type of PPE (gloves, respirator, face-shield etc)	Chemical goggles	To reduce exposure of the eye to a negligible level
Other risk management measures related to workers		
	Minimise number of staff exposed	
	Segregation of the emitting process	
	Effective contaminant extraction	
	Minimisation of manual phases	
	Avoidance of contact with contaminated tools and objects	
	Regular cleaning of equipment and work area	
	Management/supervision in place to check that the RMMs in place are being used correctly and OCs followed	
	Training for staff on good practice	
	Good standard of personal hygiene	

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Additional good practices (Operational Conditions and Risk Management Measures) beyond the REACH Chemical Safety Assessment established within Chemical Industry are also advised and communicated through Safety Data Sheets but are not necessarily required to control risk as laid out above.

2. Industrial use of ammonium nitrate for formulation of preparations, intermediate use and end-use in industrial settings, including distribution and other activities related to the processes in industrial settings

2.1. Exposure scenario

2.1.1. Description of activities and processes covered in the exposure scenario

Industrial use of ammonium nitrate for formulation of preparations, intermediate use and end-use in industrial settings: SU3/10, PC1/11/12/19/37, PROC1/2/3/5/8a/8b/9/13/15, ERC2/6a

2.1.2. Control of workers exposure

Table 5. Worst case operational conditions and risk management measures

Frequency and duration of use			
	Value	Unit	Remarks
Duration of worker exposure	> 4	hours/day	
Product characteristics			
Physical state of the substance/product	Solid/liquid	solid/liquid	
Volatility of the substance/product	low	hPa	volatility of the substance
Relative molecular weight of the substance	80.04		Needed to calculate from ppm to mg/m ³
Concentration of substance in product	-	%	Substance as such
Operational conditions not accessible for risk management			
Is the activity performed inside or outside?	Inside		
Conditions and measures at process level (source) to prevent/limit release/exposure			
Conditions and measures related to control of dispersion towards the worker			
Is local exhaust ventilation needed?	No		
Conditions and measures related to personal protective equipment and hygiene			
Is respiratory protection needed?	No		
Is skin protection needed?	No		

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According to CLP ammonium nitrate is classified as oxidizer H272 and irritating to eyes H319. Exposure of the eye to dust/splashes at concentrations leading to irritation during industrial use of ammonium nitrate can occur.

2.1.3. Risk management measures

The risk management measures related to workers can be found in Table 51. Because ammonium nitrate is irritating to eyes, the risk management measures for human health aim to avoid direct contact with the substance.

Table 6. Risk management measures related to workers at industrial sites

Information type	Data field	Explanation
Containment and local exhaust ventilation		
Containment plus good work practice required	Containment as appropriate	
Local exhaust ventilation required plus good work practise	Good standard of general ventilation	
Personal protective equipment (PPE)		
Type of PPE (gloves, respirator, face-shield etc)	Chemical goggles	To reduce exposure of the eye to a negligible level
Other risk management measures related to workers		
	Minimise number of staff exposed	
	Segregation of the emitting process	
	Effective contaminant extraction	
	Minimisation of manual phases	
	Avoidance of contact with contaminated tools and objects	
	Regular cleaning of equipment and work area	
	Management/supervision in place to check that the RMMs in	

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Information type	Data field	Explanation
	place are being used correctly and OCs followed	
	Training for staff on good practice	
	Good standard of personal hygiene	

Additional good practices (Operational Conditions and Risk Management Measures) beyond the REACH Chemical Safety Assessment established within Chemical Industry are also advised and communicated through Safety Data Sheets but are not necessarily required to control risk as laid out above.

3. Professional use of ammonium nitrate for formulation of preparations and end-use

3.1. Exposure scenario

3.1.1. Description of activities and processes covered in the exposure scenario

Professional use of ammonium nitrate for formulation of preparations and end-use: SU22, PC12, PROC1/2/8a/8b/9/11/15/19, ERC8b/8e

3.1.2. Control of workers exposure

Table 7. Worst case operational conditions and risk management measures

Frequency and duration of use			
	Value	Unit	Remarks
Duration of worker exposure	> 4	hours/day	
Product characteristics			
Physical state of the substance/product	Solid/liquid	solid/liquid	
Volatility of the substance/product	low	hPa	volatility of the substance
Relative molecular weight of the substance	80.04		Needed to calculate from ppm to mg/m ³
Concentration of substance in product	>25	%	Ammonium nitrate can occur in different concentrations in the endproducts
Operational conditions not accessible for risk management			
Is the activity performed inside or outside?	Inside/outside		
Conditions and measures at process level (source) to prevent/limit release/exposure			

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Conditions and measures related to control of dispersion towards the worker			
Is local exhaust ventilation needed?	No		
Conditions and measures related to personal protective equipment and hygiene			
Is respiratory protection needed?	No		
Is skin protection needed?	No		

According to CLP ammonium nitrate is classified as oxidizer H272 and irritating to eyes H319. Exposure of the eye to dust/splashes at concentrations leading to irritation during professional use of ammonium nitrate can occur. However, it has to be noted that the endproducts are further diluted which can lead to levels at which no eye irritation will occur.

3.1.3. Risk management measures related to professionals

Because ammonium nitrate is irritating to eyes, the risk management measures for human health should focus on the prevention of direct contact with the substance. Product related design measures preventing direct eye contact with ammonium nitrate and preventing formation of aerosols and splashes are more important in addition to the personal protective equipment measures.

Product related operational measures are required. These include specific dispensers and pumps etc specifically designed to prevent splashes/spills/exposure to occur.

Table 53 gives an overview of the personal protective equipment recommendations. The degree of restriction depends on the concentration of ammonium nitrate in the preparation.

Table 8. Risk management measures related to workers in professional settings

Information type	Data field	Explanation
Containment and local exhaust ventilation		
Containment plus good work practice required	Containment as appropriate	
Local exhaust ventilation required plus good work practise	Good standard of general ventilation	
Personal protective equipment (PPE)		
Type of PPE (gloves, respirator, face-shield etc)	Chemical goggles	To reduce exposure of the eye to a negligible level
Other risk management measures related to workers		

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Information type	Data field	Explanation
	Minimise number of staff exposed	
	Segregation of the emitting process	
	Effective contaminant extraction	
	Minimisation of manual phases	
	Avoidance of contact with contaminated tools and objects	
	Regular cleaning of equipment and work area	
	Management/supervision in place to check that the RMMs in place are being used correctly and OCs followed	
	Training for staff on good practice	
	Good standard of personal hygiene	

Additional good practices (Operational Conditions and Risk Management Measures) beyond the REACH Chemical Safety Assessment established within Chemical Industry are also advised and communicated through Safety Data Sheets but are not necessarily required to control risk as laid out above.

3.2. Exposure estimation

Not performed, qualitative assessment.

4. Consumer end-use of fertilizers and matches/fireworks

4.1. Exposure scenario

4.1.1. Description of activities and processes covered in the exposure scenario

Consumer end-use of fertilizers and matches/fireworks: SU21, PC11/12, ERC8b/8e/10a.

4.1.2. Control of consumers exposure

Table 9. Risk management measures related to consumers' use

Information type	Data field	Explanation
Personal protective equipment (PPE) required under regular conditions of consumer use		
Type of PPE (gloves, etc)	goggles	To reduce exposure of the eye to a negligible level
Instructions addressed to consumers		
	Product labelling	

According to CLP ammonium nitrate is classified as oxidizer H272 and irritating to eyes H319. Exposure of the eye to dust/splashes at concentrations leading to irritation during consumer use of ammonium nitrate can occur. However, it has to be noted that the endproducts are further diluted which can lead to levels at which no eye irritation will occur.

Exposure to eye irritating dilutions of ammonium nitrate can occur during consumer use of fertilizers. No exposure to ammonium nitrate is expected from the use of matches/fireworks. It is assumed that during normal use exposure will only occur incidentally. Furthermore, it is assumed that existing controls (i.e. personal protective equipment based on classification and labelling as H319) are applied for these exposure situations.

4.2. Exposure estimation

Not performed, qualitative assessment.